

STATEMENT OF EMERGENCY
201 KAR 8:505E

This emergency administrative regulation is necessary given that the COVID-19 pandemic has created a state of emergency in the Commonwealth and poses a risk to the health and wellbeing of Kentucky citizens. See Governor's Executive Orders 2020-215 and 2020-296. This emergency administrative regulation will allow dentists licensed through the Kentucky Board of Dentistry to administer COVID-19 vaccines authorized by the U.S. Food and Drug Administration to patients in accordance with U.S. Centers for Disease Control and Prevention and Kentucky Cabinet for Health and Family Services guidelines. Pursuant to KRS 13A.190(1)(b)(1), this emergency administrative regulation is temporary in nature and will expire as provided in this section. This emergency administrative regulation shall not be replaced by an ordinary administrative regulation because the need to administer COVID-19 vaccinations is predicated by a public health emergency, and the ongoing requirements for COVID-19 inoculation are currently unknown.

JEFF ALLEN, Executive Director
ANDY BESHEAR, Governor of Kentucky

BOARDS AND COMMISSIONS
Kentucky Board of Dentistry
(New Emergency Administrative Regulation)

201 KAR 8:505E. Administration of COVID-19 immunizations.

EFFECTIVE: January 27, 2021

RELATES TO: KRS 313.060(1)

STATUTORY AUTHORITY: KRS 313.035, 313.060(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 313.035(1) authorizes the board to promulgate administrative regulations in accordance with KRS Chapter 13A relating to dentists. KRS 313.060(1) authorizes the board to promulgate administrative regulations in accordance with KRS Chapter 13A relating to dental practices, which shall include the minimal requirements for documentation and Centers for Disease Control compliance.

Section 1. Definitions. (1) "Dental hygienist" is defined by KRS 313.010(6).

(2) "Dentist" is defined by KRS 313.010(10).

Section 2. Administration of COVID-19 Immunizations. (1) A Kentucky licensed dentist or registered dental hygienist pursuant to subsection (5) of this section may administer COVID-19 immunizations. The administration of COVID-19 immunizations shall be deemed the practice of dentistry.

(2) This administrative regulation shall not be construed to alter the scope of practice of any health care provider or authorize the delivery of health care services in a setting, or in a manner, not authorized by law. Licensees administering COVID-19 immunizations shall comply with all rules of professional conduct and state and federal statutes relevant to dentistry.

(3) Licensees shall comply with guidelines established by the U.S. Centers for Disease Control and Prevention and the Kentucky Cabinet for Health and Family Services for the administration of COVID-19 immunizations, as well as guidelines established by the federal Advisory Committee on Immunization Practices.

(4) Following the administration of a COVID-19 immunization, a licensee shall report the administration of the patient's primary care physician if applicable.

(5) Only a dental hygienist who has been granted the authority to practice local anesthesia pursuant to 201 KAR 8:562, Section 11(1) may administer a COVID-19 immunization.

Section 3. Immunization Training Course. Prior to administering COVID-19 immunizations, a licensee shall complete an immunization training program approved by the board. The course shall include, at a minimum:

(1) Educational material on the disease of COVID-19 and immunization as prevention of the disease;

(2) Contraindications and precautions for administration of the COVID-19 immunization;

(3) Intramuscular administration;

(4) Communication of the risks and benefits of the COVID-19 immunization and the legal requirements involved;

(5) Reporting of adverse events;

(6) Documentation required by federal law and the U.S. Centers for Disease Control and Prevention; and

(7) Storage and handling of COVID-19 immunizations.

Section 4. Facilities and Infrastructure. A licensee administering COVID-19 immunizations shall have immediate access to emergency response equipment, including:

(1) Oxygen administration equipment; and

(2) Epinephrine.

Section 5. Reporting Requirements. (1) The administration of a COVID-19 immunization and any adverse event following the immunization shall be reported to the Vaccine Adverse Events Reporting System (VAERS), the Kentucky Department for Public Health, and the patient's primary care physician if applicable.

(2) The licensee shall include in the patient's record:

(a) The date of administration and site of injection of the immunization;

(b) The dose, manufacturer, lot number, and beyond use date of the immunization;

(c) The name and address of the patient's primary health care provider named by the patient;

(d) A notation that the patient was presented with appropriate vaccine information prior to the administration of each vaccine; and

(e) Any adverse event that followed the immunization.

JEFF ALLEN, Executive Director

APPROVED BY AGENCY: January 27, 2021

FILED WITH LRC: January 27, 2021 at 3:46 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on April 21, 2021 at 10:30 a.m. Eastern Time via electronic hearing. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written com-

ments shall be accepted through April 30, 2021. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: Jeff Allen, Executive Director, Kentucky Board of Dentistry, 312 Whittington Parkway, Suite 101, Louisville, Kentucky 40222, phone (502) 429-7280, email jefrey.allen@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Jeff Allen

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes requirements for the administration of COVID-19 immunizations.

(b) The necessity of this administrative regulation: KRS 313.035(1) authorizes the board to promulgate administrative regulations in accordance with KRS Chapter 13A relating to dentists. KRS 313.060(1) authorizes the board to promulgate administrative regulations in accordance with KRS Chapter 13A relating to dental practices, which shall include the minimal requirements for documentation and Centers for Disease Control compliance.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation establishes requirements for the administration of COVID-19 immunizations by licensed dentists and registered dental hygienists.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation establishes requirements for the administration of COVID-19 immunizations by licensed dentists and registered dental hygienists.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: Not applicable.

(b) The necessity of the amendment to this administrative regulation: Not applicable.

(c) How the amendment conforms to the content of the authorizing statutes: Not applicable.

(d) How the amendment will assist in the effective administration of the statutes: Not applicable.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This regulation will primarily affect the approximately three thousand prescribing dentists licensed in Kentucky and patients receiving COVID-19 immunizations by licensed dentists and registered dental hygienists.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it an amendment, including:

(a) List the actions that each of the related entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Each licensee, if providing immunization services, will be required to provide such services in accordance with applicable law and administrative regulations.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): No costs will be accrued as a result of the new administrative regulation, other than set-up costs for the administration of immunizations.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The administrative regulation will result in a healthier patient population.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

- (a) Initially: No cost.
- (b) On a continuing basis: No cost.
- (6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation? Not applicable.
- (7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No.
- (8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: No.
- (9) TIERING: Is tiering applied? No; this administrative regulation impacts all similarly situated practitioners equally.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

- (1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? None.
 - (2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 313.035; KRS 313.060(1).
 - (3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.
 - (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? None.
 - (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? None.
 - (c) How much will it cost to administer this program for the first year? No cost.
 - (d) How much will it cost to administer this program for subsequent years? No cost.
- Note: If specific dollar amounts cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.
- Revenues (+/-): None.
- Expenditures (+/-): None.
- Other explanation: Not applicable.